IN THE SPECIFICATION

The Descriptive Title of the Invention has been amended as follows:

Composite Stent with Regioselective Material and a Method of Forming the Same

Please insert the following section before the "**FIELD OF THE INVENTION**" section beginning on page 1:

CROSS REFERENCE

This is a divisional application of U.S. Serial Number 09/895,753, which was filed on June 29, 2001.

Paragraph 8 beginning on page 5 has been amended as follows:

[0008] FIG. 1 is an illustration of a stent according to one embodiment of the present invention.

Paragraph 18 beginning on page 7 has been amended as follows:

[0018] In one embodiment, the material or materials used to form regioselective bands 209 or strips (not shown) are viscoelastic materials having a high creep compliance because such materials are easily expandable and typically exert a gradual and weak restoring force that avoids collapsing or substantially deforming an expanded stent over time. In one embodiment, the creep compliance may be approximately 0.3846 Giga-Pascals $(GPa)^{-1}$ and may range from approximately 0.5 GPa^{-1} to approximately 10.0 GPa^{-1}. In another embodiment, elastic materials may be used provided care is taken to ensure that the stent in its expanded state is capable of sustaining the elastic material's immediate and strong restoring force without collapsing or substantially deforming the expanded stent over time. ~~For a general discussion of creep compliance, modulus of elasticity, and viscoelastic materials, please see, Technical paper by~~

~~Bohlin Instruments, Inc. of East Brunswick, NJ, located at http:/www.bohlinusa.com/technicalnotes.asp; *Viscoelastic Notes* by Rod Lakes located at http:/silver.neep.wisc.edu/~lakes/Venotes.html, which were adapted from the book *Viscoelastic Solids; and Fundamentals of Physics*, Fourth Edition (1993), by David Halliday, *et al.*, pp. 366-367.~~

Paragraph 19 beginning on page 8 has been amended as follows:

[0019] Anti-proliferative drugs, anti-platelet drugs, TB3A inhibitors, and ~~nitrate~~<u>nictric</u> oxide donors, bioactive drugs, blood compatible matrices, and radioactive emitters may be incorporated in the structural and/or regioselective materials forming stent 200. In one embodiment, the blood compatible matrices and bioactive drugs may be bio-absorbable. Substances that may be incorporated in a stent or its components to make the stent visible under a fluoroscope include heavy rare earth metals such as gold, micronized tantalum, platinum-iridium, and similar materials. Examples of blood compatible matrices and bioactive drugs that may be used to form a regioselective band 209 or a regioselective strip illustratively include:

a. DUROFLO® or other coatable Heparin Derivative (In this case, the drug itself can form the regioselective material);

b. Phosphoryl choline;

c. Ethylene vinyl alcohol (EVAL);

d. ~~Polyvanhydrides~~<u>Polyanhydrides</u>;

e. ~~Polyoxaesters~~<u>Polyesters</u>;

f. Polyphosphazenes;

g. ~~Polyhydroxybutarate~~<u>Polyhydroxybutyrate</u>;

h. Valerate (PHB, PHV) (these ~~matries~~<u>materials</u> belong to an absorbable family);

i. ~~Polyeurethanes~~Polyurethanes such as Biospan®, Biospan-S®, Biospan P®, and Elastion~~, and~~;

j. ~~Poly vinyledene~~Polyvinylidene fluoride (PVDF);

k. Poly (butyl methacrylate) (PBMA);

l. Kraton™;

m. Hexafluoropropylene (PDF-6-HEFP);

n. Hyaluronic Acid;

o. Water soluble ~~chondroitan~~chondroitin sulfate;

p. Poly (ethylene glycol) (PEG), Poly (Vinyl Pyrrolidine) (PVP);

q. PCL-CO-PEG, PLA-CO-PEG; polybutylene tarephthalate (Polyactive) (these materials belong to an absorbable blood compatible family); and

r. Poly alpha-hydroxy acids (PLA, PCL, PGA, etc.).

Paragraph 22 beginning on page 10 has been amended as follows:

[0022] In one embodiment, regioselective bands 209 or regioselective strips 302 may be preformed and then affixed to a stent using a biocompatible medical adhesive. Fibrin glue, cyanoacrylate, ~~focal seal~~FocalSeal®, carboxymethyl cellulose, gelatin-~~resourcin~~resorcin-formaldehyde glue (GRF), silk elastin, tropoelastin added with an *in situ* cross-linker such as lysine peroxidase and similar materials, water soluble ~~chondroitan~~chondroitin sulfate, are examples of biocompatible adhesives that may be used.

Paragraph 24 beginning on page 11 has been amended as follows:

[0024] At Block 403, the solution is dripped onto the rotating stent such that a semi-solid or solid conformal band results after one or more complete revolutions of the stent. In one embodiment, the viscosity of the solution is such that the solution streams from the drip nozzle

like a liquid fiber and loops about the stent to form a concentric annular band having a substantially tubular diameter of approximately 0.5 to approximately 5.0 microns. In another embodiment, the viscosity of the solution is such that the solution streams from the drip nozzle like a liquid fiber and spreads somewhat laterally across a discrete portion of the stent to form a conformal band of substantially uniform width of approximately 0.5 mm to about 3.0 mm, and a variable elastic or semi-elastic thickness of approximately 1.0 to approximately 5.0 microns when cured. At Block 404, the flow of viscous solution is stopped, and the band is cured by either washing away the solvent, or by air-drying the band. At Block 405, the process may be repeated at the same or another discrete area of the stent until a desired dosimetry profile and/or regioselective thickness is achieved. At Block 406, the stent may be sterilized with radiation, heat, or chemicals. Because individual therapeutic agents degrade at different temperatures and react differently when brought into contact with radiation or chemicals, care should be taken to ensure that the sterilization method used does not adversely affect the therapeutic agent incorporated in the regioselective material. In one embodiment, ~~a~~an electron beam sterilization method is used in which the stent is subjected to a 3.5 Mrad. At Block 407, the stent may be packaged in a sterile container for delivery to a user.

Paragraph 27 beginning on page 13 has been amended as follows:

[0027] With reference to the methods described above, the distance separating the outer surface of the stent from the tip of the drip nozzle may vary depending on the viscosity of the solution, the air temperature, and the air humidity. For example, very dry hot air may necessitate placing the stent close to the drip nozzle to prevent the viscous solution from drying too quickly. Alternatively, if the air is cool and humid, the stent may be placed further away from the drip nozzle. Similarly, using a very viscous solution may necessitate placing the stent close to the drip nozzle to avoid unnecessarily stretching the solution via free fall. Alternatively, using a

less viscous solution may allow the stent to be placed further away from the drip nozzle. In one embodiment, a viscosity of approximately 100 ~~Centi-Poise~~centipoises (cP) at room temperature is used with a distance of approximately 5.0 cm separating the stent from the drip nozzle. Illustratively, the viscosity may range from approximately 5.0 ~~cm~~cP to 1,000 cP at room temperature, and the distance may range from approximately 1.0 cm to approximately 15.0 cm. In another embodiment, a viscosity of approximately 50.0 cP to approximately 500 cP at room temperature is used, with a distance of approximately 3.0 cm to approximately 8.0 cm separating the stent from the drip nozzle.

Paragraph 30 beginning on page 14 has been amended as follows:

[0030] Fig. 6 illustrates one embodiment of an alternate method of uniformly and integrally coating a discrete ~~are~~area of a stent with a regioselective material containing a therapeutic agent. In one embodiment, the discrete area of the stent is a band ranging from approximately 0.5 microns wide up to and including the entire length of the stent. The method begins at Block 601 by preparing a solution of PCL and/or poly ethylene glycol (PEG) containing a dissolved or suspended thrombotic agent as described above, and placing the solution in an open container. The viscosity of the solution is chosen such that the coating will uniformly and integrally spread along the surface area of the stent when the stent is spun in a centrifuge. At Block 602, a portion of the stent to be coated is dipped into the viscous solution and removed. Alternatively, a discrete portion of the stent may be coated with the solution using a spraying or brushing method. At Block 603, the stent is secured in a centrifuge and spun to spread the solution uniformly and integrally along a portion of the stent. At Block 604, the stent is removed from the centrifuge and cured either by allowing it to air-dry, or by coating it with a solvent, such as ~~Methanol~~methanol. At Block 605, the process may be repeated at the same or another discrete area of the stent until a desired dosimetry profile and/or regioselective thickness is achieved. At

Block 606, the stent may be sterilized with radiation, heat, or chemicals. Because individual therapeutic agents degrade at different temperatures and react differently when brought into contact with radiation or chemicals, care should be taken to ensure that the sterilization method used does not adversely affect the therapeutic agent incorporated into the regioselective material. In one embodiment, an electron beam sterilization method is used in which the stent is subjected to approximately 3.5 MRad. At Block 607, the stent may be packaged in a sterile container for delivery to a user. While the above method was illustratively described with reference to a single stent, it should be noted that the method may be used to process multiple stents simultaneously, as previously described.

Paragraph 31 beginning on page 15 has been amended as follows:

[0031] With reference to the centrifugation method described above, a viscosity of approximately 100~~CP~~ cP at room temperature is used, with a rotational speed of approximately 7,000 rev/min for approximately 1.0 min. Illustratively, the viscosity may range from approximately 100 ~~CP~~cP to approximately ~~1000 CP~~1,000 cP at room temperature with rotational speeds in the range of approximately 2,000 rev/min to approximately 10,000 rev/min and times of approximately 20.0 seconds to approximately 2.0 min. The ~~rotation~~rotational speed of the centrifuge, the viscosity of the composition, the air temperature and humidity inside the centrifuge, and time of rotation may be adjusted as desired to modify the band layers. For example, a very viscous material may require higher rotational speeds and longer drying times than a low viscous material.